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| APPLICATION NO.              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 10/511,495                   | 01/03/2006  | Mahyar Z Kermani     | LFS-5004USNP        | 4593             |
| 27777                        | 7590        | 07/31/2007           | EXAMINER            |                  |
| PHILIP S. JOHNSON            |             |                      | PANI, JOHN          |                  |
| JOHNSON & JOHNSON            |             |                      | ART UNIT            |                  |
| ONE JOHNSON & JOHNSON PLAZA  |             |                      | PAPER NUMBER        |                  |
| NEW BRUNSWICK, NJ 08933-7003 |             |                      | 3736                |                  |
|                              |             |                      | MAIL DATE           | DELIVERY MODE    |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/511,495

Applicant(s)

KERMANI ET AL.

Examiner

John Pani

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/14/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/10/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

1. Claims 1, 13, 18 and 24 are objected to because of the following informalities:

#### In reference to Claim 1

It appears "skin piercing element" in line 5 should be changed to --skin-piercing element—in order to maintain consistency.

#### In reference to Claim 13

It appears "skin piercing element" in line 6 should be changed to --skin-piercing element—in order to maintain consistency.

#### In reference to Claim 18

It appears "second electrical contacts" in line 2 should be changed to --second electrical contact— .

#### In reference to Claim 24

It appears "micron-needle" in line 2 should be changed to --micro-needle—in order to maintain consistency.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-7, 10-12, and 19-25 are rejected under 35 U.S.C. 102(e) as being anticipated by US2003/0083641 to Angel et al. (Angel).

4. Angel teaches:

In reference to Claims 1, 7, and 11

A system (12) for piercing dermal tissue, the system comprising a skin-piercing element that is a microneedle (microneedle 14); at least one electrical contact (a second microneedle 14, see Fig. 2A); and a meter (impedance sensor 32) configured for measuring an electrical characteristic existent ("impedance") between the skin-piercing element and the at least one electrical contact when the system is in use (see [0045]).

In reference to Claim 2

The system of claim 1 (see above), wherein the at least one electrical contact is an electrical skin contact (The microneedles both contact the skin electrically, see [0045]).

In reference to Claim 3

The system of claim 1 (see above), wherein the meter is configured to measure an electrical characteristic (impedance) between the skin-piercing element and the at least one electrical contact that is indicative of dermal tissue penetration by the skin-piercing element (see [0045]).

In reference to Claim 4

The system of claim 1 (see above), wherein the meter is configured to measure an electrical characteristic (impedance over time, see Fig. 9A) between the skin-piercing element and the at least one electrical contact that is indicative of a stability of dermal tissue penetration by the skin-piercing element (The impedance over time is inherently indicative of the stability of penetration, as the impedance varies with stability).

In reference to Claim 5

The system of claim 1 (see above), wherein the meter is configured to measure an electrical characteristic (impedance over time, see Fig. 9A) between the skin-piercing element and the at least one electrical contact that is indicative of dermal tissue penetration residence time by the skin-piercing element (The impedance over time is inherently indicative of the needle residence time, as the impedance is much higher when the contacts are in the skin than when they are not properly located).

In reference to Claim 6

The system of claim 1; wherein the electrical characteristic is the electrical resistance (Resistance is the real part of the impedance, which is measured) between the skin-piercing element (14) and the at least one electrical contact (second 14).

In reference to Claim 10

The system of claim 1 (see above), wherein the meter includes a pressure/contact ring (base portion 36) and the at least one electrical contact is integrated with the pressure/contact ring (The micro-needles 14 are located in a ring-shaped structure that applies pressure to the skin, see Fig. 2A).

In reference to Claim 12

The system of claim 11 (see above), wherein the micro-needle (14) is a component of an integrated (see Fig. 2A) micro-needle and biosensor medical device (Reservoir 46 can contain a reagent for causing a reaction, i.e. to act as a biosensor, or additionally, see [0098]).

In reference to Claims 19 and 23

A method for piercing dermal tissue comprising: contacting a dermal tissue (see [0045]) with at least one electrical contact (14); and inserting a skin-piercing element that is a microneedle (a second microneedle 14) into the dermal tissue while measuring an electrical characteristic (impedance) existent between the skin-piercing element (14) and the at least one electrical contact (a second microneedle 14), thereby penetrating the dermal tissue (see [0045]).

In reference to Claim 20

The method of claim 19 (see above), further including the step of presenting a user with an indicator of a dermal tissue penetration depth (see Fig. 9B and [0096]) of the skin-piercing element, said indicator being based on the measured electrical characteristic (measured impedance).

In reference to Claim 21

The method of claim 19 (see above), further including the step of presenting a user with an indicator of a dermal tissue penetration stability (see Fig. 9A of the skin-piercing element. Variations of the impedance on this graph are indicators of penetration stability, for example, greater fluctuations indicate lower stability) said indicator being based on the measured electrical characteristic (measured impedance).

In reference to Claim 22

The method of claim 19 (see above), further including the step of presenting a user with an indicator of a dermal tissue penetration residence time (see Fig. 9A of the skin-piercing element. Impedance is greatest before penetration and higher after penetration has begun. See also [0096]) said indicator being based on the measured electrical characteristic (measured impedance).

In reference to Claim 24

The method of claim 19 (see above), wherein the inserting step includes inserting (see [0045]) a micro-needle (14) of an integrated (see Fig. 2A) micro-needle and biosensor medical device (Reservoir 46 can contain a reagent for causing a reaction, i.e. to act as a biosensor, or additionally, see [0098]).

In reference to Claim 25

The method of claim 19 (see above), wherein the inserting step further involves measuring the electrical characteristic (impedance) prior to contact between the skin-piercing element (14) and the dermal tissue, when the skin-piercing element has contacted the dermal tissue, and when the skin-piercing element has penetrated the dermal tissue (see [0096]).

5. Claims 1, 8-9, 13-14, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by US2003/0216661 to Davies (Davies).
6. Davies teaches:

In reference to Claim 1

A system for piercing dermal tissue, the system comprising a skin-piercing element (nipple electrode **430**, or intravenous electrode, see [0065]); at least one electrical contact (probe **400**); and a meter (measurement device **420**) configured for measuring an electrical characteristic (DC electropotential and impedance, see [0065]) existent between the skin-piercing element **430** and the at least one electrical contact **400** when the system is in use.

In reference to Claim 8

The system of claim 1 (see above), wherein the at least one electrical contact (**400**) includes a first electrical contact (**451**) and a second electrical contact (**452**).

In reference to Claim 9

The system of claim 8 (see above), wherein the meter is further configured for measuring an electrical characteristic existent between the first (**451**) and second (**452**) electrical contacts (see [0069], current is passed in **452** and measured by **451**).

In reference to Claim 13

A system for piercing dermal tissue, the system comprising: a skin-piercing element (nipple electrode **430**, or intravenous electrode, see [0065]); a first electrical contact (**451**); a second electrical contact (**452**); and a meter (**420**) configured for measuring an electrical characteristic (impedance) existent between the skin piercing element and the first and second electrical contacts when the system is in use (Impedance is measured between **451** and **452** and both are referenced to **430**, see [0069] and [0065]).



In reference to Claim 14

The system of claim 13 (see above), wherein the electrical characteristic is the electrical impedance between the skin-piercing element (**430**) and both of the first (**451**) and second (**452**) electrical contacts (Impedance is measured between **451** and **452** and both are referenced to **430**, see [0069] and [0065]).

In reference to Claim 18

The system of claim 13, wherein the first electrical contact (**451**) is a first electrical skin contact and the second electrical contact (**452**) is a second electrical skin contact (see Fig. 4A).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 13, 15-17, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Angel in view of US2002/0065481 to Cory et al. (Cory).

In reference to Claim 13

Angel teaches a system (**12**) for piercing dermal tissue, the system comprising a skin-piercing element (microneedle **14**); a first electrical contact (a second microneedle **14**, see Fig. 2A); and a meter (impedance sensor **32**) configured for measuring an electrical characteristic existent ("impedance") between the skin-piercing element and

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the first electrical contact when the system is in use (see [0045]). However, Angel does not teach a second electrical contact or a meter configured to measure an electrical characteristic between the skin-piercing element and the second electrical contact.

Cory teaches of a nerve stimulator that uses electrical resistance to measure penetration depth, in which a needle **107** that includes electrically conducting surfaces penetrates the skin, and a return electrode **135** is placed on the skin (see Fig. 2 and [0052]).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device taught by Angel by adding a reference electrode placed on the surface of the skin, as taught by Cory, so that the insertion depth of the individual microneedles taught by Angel could be further calculated using the process taught by Cory.

In reference to Claim 15

Angel in view of Cory teaches the system of claim 13 (see above), and Angel further teaches a pressure/contact ring (base portion **36**) in which the first electrical contact is integrated with the pressure/contact ring (The micro-needles **14** are located in a ring-shaped structure that applies pressure to the skin, see Fig. 2A).

It would have been further obvious to one having ordinary skill in the art at the time of the invention when modifying Angel by Cory as in claim 14 (see above) to have included a surface reference electrode as taught by Cory, in the base portion **36** taught by Angel, as this would provide a reference electrode that was already in contact with the section of skin that was being examined when the device is in use.

In reference to Claim 16

Angel in view of Cory teaches the system of claim 13 (see above), and Angel further teaches the skin-piercing element is a micro-needle (microneedle **14**).

In reference to Claim 17

Angel in view of Cory teaches the system of claim 16 (see above), and Angel further teaches that the micro-needle (**14**) is a component of an integrated (see Fig. 2A) micro-needle and biosensor medical device (Reservoir **46** can contain a reagent for causing a reaction, i.e. to act as a biosensor, or additionally, see [0098]).

In reference to Claim 26

Angel teaches a method of claim 19 (see above), but does not mention what range of current is applied.

Cory teaches of a nerve stimulator that uses a similar circuit for both nerve stimulation and for determining needle insertion depth (see [0051]). The circuit supplies a current of 1-2 mA (see [0048]).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an applied current of 1-2 mA for measuring in the device of Angel, because this range is known to be appropriate for application to skin, as implicitly taught by Cory.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Angel in view of US Pat. No. 5,069,223 to McRae (McRae).

Angel teaches the method of claim 19 (see above), but does not mention the frequency range of the applied potential.

McRae teaches of a method for measuring the impedance of tissue in which impedance is measured by applying a potential in a frequency range of 10KHz to 30MHz (col. 3 lines 1-20).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an applied potential of 10KHz to 30 KHz for measuring in the device of Angel, because this range is known to be appropriate for application to skin, as implicitly taught by McRae.

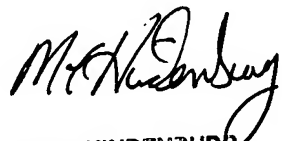
Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Pani whose telephone number is 571-270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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